



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,615	08/25/1999	EDWARD L. SINOFSKY	101327-126	5467

21125 7590 03/24/2004

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/382,615

Applicant(s)

SinoPhy

Examiner

d. shay

Group Art Unit

3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on November 20, 2003
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1 + 3-24 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1 + 3-24 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 3739

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-12, 15, 16, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven. Kittrell et al teach a device as claimed except for the particular deflection member. Heaven teaches a deflection member (see figure 1) which has an outer sheath (14), a cut out and, when viewed in profile, an hourglass shape wherein the width of the cut away portion is less than the diameter of the non-cut away portion. It would have been obvious to insert the device of Kittrell et al into the device of Heaven or to employ the elongate and the deflection member of Heaven in the device of Kittrell et al in place of, for example, element 140 in figure 14, since Kittrell et al envision a wide variety of deflection mechanisms; to provide multiple deflection members to allow deflection in multiple directions; and to form the deflection member so as to run from the proximal end of the catheter, since this would provide greater strength as shown by Heaven, thereby rendering the cutout at the distal end of the deflection member, and to form the member or surround the member with a fluoropolymer, since these are notorious for use in catheters and provide a lubricious surface, official notice which has already been taken, and to provide the particular location of the cutout, since this is not critical and provides no unexpected result, thus producing a device such as claimed.

Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heaven in combination with Kittrell et al. The teachings of Heaven and Kittrell et al and the motivation for modification and combination thereof are essentially those already set forth above. It would have been obvious to the artisan of ordinary skill to repeatedly advance the fiber device of Kittrell et al when it is inserted through the tubular member of Heaven, since Kittrell et al a

Art Unit: 3739

specify the device is to be advanced through the lumen until the obstruction is removed, thus producing a method such as claimed.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven as applied to claim 12 above, and further in view of Vassiliadis et al. Vassiliadis et al teach the use of a gold coating on a laser applicator. It would have been obvious to the artisan of ordinary skill to employ a gold coating, as taught by Vassiliadis, since this would protect tissue from unintended irradiation, thus producing a device such as claimed.

Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kittrell et al in combination with Heaven as applied to claims 17-21 are above, and further in view of Isner et al. Isner et al teach a method of treating tachycardia including inserting a catheter and inserting a fiber therein for applying laser energy to the foci responsible for the tachycardia. It would have been obvious to the artisan of ordinary skill to employ the tachycardia treatment method of Isner et al in the surgical device placement method of Heaven, since Heaven teach that the device can be used with a variety of medical procedures thus producing a method such as claimed.

Applicant argues that one of ordinary skill would not combine the teachings of Heaven and Kittrell et al, alleging that "Heaven does not even suggest using the catheter with an ablation instrument". The examiner must respectfully disagree. The disclosure of Heaven makes it abundantly clear that the device disclosed therein is to be used with medical devices in general (see e.g. column 4, lines 20-24) and particularly for catheters (see the Abstract). Clearly the device of Kittrell et al falls into this classification: "A laser catheter is disclosed... (see the

Art Unit: 3739

Abstract of Kittrell et al). Thus one having ordinary skill would not hesitate to combine the two teachings.

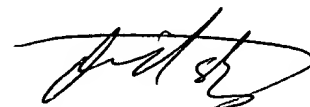
Applicant has amended the claims to recite a tapered distal end. With the understanding that the originally submitted informal drawings render discerning the exact form of the various embodiments somewhat challenging, it appears that this limitation refers to the taper associated with the hour glass shape of figures 10 and 11, this is presumed correct since claim 7, dependent on claim 1, recites the hour glass shape. However Heaven teaches the concept of tapering (see Figures 5 and 6 and column 5, lines 51-63).

Further applicant argues that the combination of Heaven and Kittrell et al would result in the laser catheter of Kittrell et al being situated in the interior lumen of the device of Heaven and would thus not meet the claim limitation "a deflection member disposed within the first lumen of the flexible elongate member..." The examiner must respectfully disagree for the following reasons: firstly Heaven teaches the use of an external flexible elongate member (see element 14, Figures 2 and 3) and secondly, Kittrell et al disclose that the laser catheter therein may be used in conjunction with an external catheter (see Figure 14 and column 15, lines 30-48). Either of these situations would entail a device wherein the deflection member is disposed within a lumen of a flexible elongate member as claimed.

Applicant's arguments filed November 20, 2003 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

Shay/DI; March 8, 2004



DAVID M. SHAY
PRIMARY EXAMINER
R011P 330